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| EXAMINER | |
|---|---|
| MARTINEZ, BRITTANY M | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/562,526 | CHANE-CHING ET AL. | |
| | Examiner | Art Unit | |
| | BRITTANY M. MARTINEZ | 1734 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *June 21, 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9-15,17 and 19-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-15, 17 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on June 21, 2010, has been entered.

### *Status of Application*

Acknowledgment is made of Applicants' arguments/remarks and amendment filed on June 21, 2010. **Claims 1-7, 9-15, 17 and 19-22** are pending in the instant application, with **Claims 1, 10 and 11** amended. **Claims 1-7, 9-15, 17 and 19-22** have been examined. **Claims 8, 16 and 18** have been cancelled.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 1, 10 and 11** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter

which was not described in the original Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the original disclosure for the amended portion of **Claims 1, 10 and 11** that reads "at least 80% of the calcium phosphate platelets have a length of between 250 nm and 800 nm." The relevant portions of the original Specification recite "at least 80%...by weight of the platelets according to the invention have an equivalent diameter of less than or equal to 200 nm" (S. p. 3, l. 21-26); "60% by number of the platelets according to the invention have a size of less than or equal to 500 nm,...advantageously 80%" (S. p. 5, l. 21-24); and "at least 80% by number of the platelets have a length of between 250 nm and 600 nm, preferably of between 250 nm and 400 nm" (S. p. 7, l. 15-18).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 1-7, 10 and 11** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

5. With regard to **Claims 1, 10 and 11**, the phrase "highly crystalline" is relative terminology which renders the Claims indefinite. The phrase "highly crystalline" is not defined by the Claims, the Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purposes of examination, "highly crystalline" was interpreted as "crystalline" or "crystals."

6. With regard to **Claims 1, 10 and 11**, it is unclear whether the "at least 80%" refers to a weight percentage or a number percentage since the instant Specification enumerates embodiments that use "by weight" (S. p. 3, l. 21-26) and "by number" (S. p. 5, l. 21-24; p. 7, l. 15-18).

7. With regard to **Claims 2-7**, it is unclear whether "The composition comprising separated calcium phosphate platelets according to claim 1 [or 3]" is intended to refer to the separated, highly crystalline calcium phosphate platelets of **Claim 1 [or 3]**, or the "composition comprising an aqueous dispersion of separated, highly crystalline calcium phosphate platelets" of **Claim 1 [or 3]**. If said portion of **Claims 2-7** is intended to refer to the separated, highly crystalline calcium phosphate platelets of **Claim 1 [or 3]**, "The composition" in **Claims 2-7** should be changed to "A composition." If said portion of **Claims 2-7** is intended to refer to the "composition comprising an aqueous dispersion of separated, highly crystalline calcium phosphate platelets" of **Claim 1 [or 3]**, "an aqueous dispersion of" should be inserted after "composition comprising" in **Claims 2-7**.

### *Claim Rejections - 35 USC § 102*

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-3, 5, 7 and 9** are rejected under 35 U.S.C. 102(b) as being anticipated by Itoi et al. (US 6,159,437) (of record).

10. With regard to **Claims 1-3**, Itoi et al. disclose a composition comprising an aqueous dispersion (Itoi et al., c. 2, l. 55-57; c. 3, l. 21-27 and 36-65) of separated crystalline calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a short axis length of 30 to 300 nm and a long-axis length of 100 to 1000 nm (Itoi et al., c. 2, l. 55-57; c. 3, l. 21-31). Itoi et al. do not explicitly disclose "highly" crystalline calcium phosphate, deficient apatite structure, or at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

11. With regard to the "highly" crystalline calcium phosphate of **Claim 1**, "highly crystalline" was interpreted as "crystalline" or "crystals" since "highly crystalline" is not defined by the Claims, the Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. *See* 35 U.S.C. 112, second paragraph, rejection above. Thus, the crystalline calcium phosphate platelets of Itoi et al. would be "highly crystalline." In any event, no other calcium phosphate structure besides crystalline is disclosed by Itoi et al. and thus, the crystalline calcium phosphate platelets of Itoi et al. would be "highly crystalline" because of the absence of any other calcium phosphate structure.

12. With regard to the deficient apatite structure of **Claim 1**, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P

ratio of 1.25-1.67 (as evidenced by the instant Specification, S. 0023), and Itoi et al. discloses hydroxyapatite (Itoi et al., c. 2, l. 55-57), $Ca_{10}(PO_4)_6(OH)_2$, which has a Ca/P molar ratio of 1.67. Thus, the calcium phosphate of Itoi et al. would have deficient apatite structure to no less an extent than that of the instant application.

13. With regard to the at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claim 1**, Itoi et al. disclose apatite crystals with a short axis length of 30 to 300 nm and a long-axis length of 100 to 1000 nm (Itoi et al., c. 3, l. 29-31). At least 80% of the calcium phosphate platelets of Itoi et al. would inherently have a length of between 250 nm and 800 nm. For a reference which neither expressly describes or teaches the subject matter alleged to be anticipated, the reference must provide enough information to permit an inference that the subject matter is inherent. *Ex parte Garvin*, 62 USPQ 2d 1680 (BPAI 2001). If the average particle size of the calcium phosphate platelets of Itoi et al. in the range of 100 to 1000 nm is 500 nm, then at least 80% of the calcium phosphate platelets of Itoi et al. would most surely have a length of between 250 nm and 800 nm. Accordingly, the burden shifts to Applicants to show that the calcium phosphate platelets of Itoi et al. would not have at least 80% of the calcium phosphate platelets with a length of between 250 nm and 800 nm.

14. With regard to **Claim 5**, Itoi et al. disclose a plurality of the platelets having an apatite structure (Itoi et al., c. 2, l. 55-57; c. 3, l. 21-27). Although Itoi et al. do not explicitly disclose the platelets exhibiting a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR, the platelets of Itoi et al. would be

expected to exhibit a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR since the platelets of Itoi et al. have an apatite structure.

15. With regard to **Claim 7**, Itoi et al. disclose hydroxyapatite (Itoi et al., c. 2, l. 55-57), $Ca_{10}(PO_4)_6(OH)_2$, which has a Ca/P molar ratio of 1.67.

16. With regard to **Claim 9**, Itoi et al. disclose a colloidal dispersion comprising calcium phosphate platelets in an aqueous solution containing a dispersing agent (Itoi et al., c. 2, l. 55-57; c. 3, l. 21-27 and 36-65).

17. **Claims 1 and 2** are rejected under 35 U.S.C. 102(a) as being anticipated by Roeder et al. (US 2003/0031698 A1) (of record).

18. With regard to **Claims 1 and 2**, Roeder et al. disclose a composition comprising an aqueous dispersion of separated crystalline calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a mean length of between 1 nm and 500 nm (Roeder et al., "Abstract;" Fig. 2; Table 1; 0014; 0031; 0033; 0035; 0047). Roeder et al. do not explicitly disclose "highly" crystalline calcium phosphate or at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

19. With regard to the "highly" crystalline calcium phosphate of **Claim 1**, "highly crystalline" was interpreted as "crystalline" or "crystals" since "highly crystalline" is not defined by the Claims, the Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. *See* 35 U.S.C. 112, second paragraph, rejection above.

Thus, the crystalline calcium phosphate platelets of Roeder et al. would be "highly crystalline." In any event, no other calcium phosphate structure besides crystalline is disclosed by Roeder et al. and thus, the crystalline calcium phosphate platelets of Roeder et al. would be "highly crystalline" because of the absence of any other calcium phosphate structure.

20. With regard to the at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claim 1**, Roeder et al. disclose the calcium phosphate platelets have a mean length of between 1 nm and 500 nm (Roeder et al., 0035). At least 80% of the calcium phosphate platelets of Roeder et al. would inherently have a length of between 250 nm and 800 nm. For a reference which neither expressly describes or teaches the subject matter alleged to be anticipated, the reference must provide enough information to permit an inference that the subject matter is inherent. *Ex parte Garvin*, 62 USPQ 2d 1680 (BPAI 2001). If the average particle size of the calcium phosphate platelets of Roeder et al. in the range of 1 nm and 500 nm is 480-500 nm, then at least 80% of the calcium phosphate platelets of Roeder et al. would most surely have a length of between 250 nm and 800 nm. Accordingly, the burden shifts to Applicants to show that the calcium phosphate platelets of Roeder et al. would not have at least 80% of the calcium phosphate platelets with a length of between 250 nm and 800 nm.

***Claim Rejections - 35 USC § 103***

21. **Claims 1-3, 5, 7 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoi et al. (US 6,159,437) (of record).

22. With regard to **Claims 1-3**, Itoi et al. is applied as above. Itoi et al. do not explicitly disclose "highly" crystalline calcium phosphate, deficient apatite structure, or at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

23. With regard to the "highly" crystalline calcium phosphate of **Claim 1**, "highly crystalline" was interpreted as "crystalline" or "crystals" since "highly crystalline" is not defined by the Claims, the Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. *See* 35 U.S.C. 112, second paragraph, rejection above. Thus, the crystalline calcium phosphate platelets of Itoi et al. would be "highly crystalline." In any event, no other calcium phosphate structure besides crystalline is disclosed by Itoi et al. and thus, the crystalline calcium phosphate platelets of Itoi et al. would be "highly crystalline" because of the absence of any other calcium phosphate structure.

24. With regard to the deficient apatite structure of **Claim 1**, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (as evidenced by the instant Specification, S. 0023), and Itoi et al. discloses hydroxyapatite (Itoi et al., c. 2, l. 55-57), $Ca_{10}(PO_4)_6(OH)_2$, which has a Ca/P

molar ratio of 1.67. Thus, the calcium phosphate of Itoi et al. would have deficient apatite structure to no less an extent than that of the instant application.

25. With regard to the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claim 1**, the claimed particle size range overlaps the range disclosed by Itoi et al. and thus, a *prima facie* case of obviousness exists. *See* In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). Optimization of the platelet size range would have been obvious to one of ordinary skill in the art. *See* Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

26. With regard to the at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claim 1**, Itoi et al. disclose apatite crystals with a short axis length of 30 to 300 nm and a long-axis length of 100 to 1000 nm (Itoi et al., c. 3, l. 29-31). If the average particle size of the calcium phosphate platelets of Itoi et al. in the range of 100 to 1000 nm is 500 nm, then at least 80% of the calcium phosphate platelets of Itoi et al. would most surely have a length of between 250 nm and 800 nm. In any event, optimization of the platelet size would have been obvious to one of ordinary skill in the art.

27. With regard to **Claim 5**, Itoi et al. is applied as above. Although Itoi et al. do not explicitly disclose the platelets exhibiting a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR, the platelets of Itoi et al. would be expected to exhibit a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR since the platelets of Itoi et al. have an apatite structure.

28. With regard to **Claim 7**, Itoi et al. is applied as above.

29. With regard to **Claim 9**, Itoi et al. is applied as above.

30. **Claims 1-4, 6, 9-15, 17 and 19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Roeder et al. (US 2003/0031698 A1) (of record).

31. With regard to **Claims 1 and 2**, Roeder et al. is applied as above. Roeder et al. do not explicitly disclose "highly" crystalline calcium phosphate or at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

32. With regard to **Claim 4**, Roeder et al. disclose a plurality of the platelets having a monetite structure (Roeder et al., "Abstract;" Fig. 2; Table 1; p. 2, 0014; p. 3, 0033 and 0035; p. 5, 0047).

33. With regard to **Claim 6**, Roeder et al. disclose monetite (Roeder et al., Table 1), $CaHPO_4$, which has a Ca/P molar ratio of 1.

34. With regard to **Claim 9**, Roeder et al. disclose a colloidal dispersion comprising calcium phosphate platelets in an aqueous solution containing a dispersing agent (Roeder et al., p. 3, 0031).

35. With regard to **Claims 10-15, 17 and 19-22**, Roeder et al. disclose a method of preparing an aqueous dispersion of crystalline, separated calcium phosphate platelets which exhibit monetite structure and have a mean length of between 1 nm and 500 nm (Roeder et al., "Abstract;" Fig. 2; Table 1; 0014; 0031; 0033; 0035; 0047), wherein the method comprises the steps of preparing solutions of calcium salt (calcium nitrate or calcium chloride), pH modifying precursors, and phosphate solution (ammonium orthophosphate or the like); heat treating the solution at a temperature from about 37°C to about 200°C; separating the calcium phosphate formed from the solution; and preparing the dispersion of calcium phosphate platelets in the aqueous solvent (water) (Roeder et al., "Abstract;" Fig. 2; Table 1; 0014; 0031; 0033; 0035; 0044-0050). Roeder et al. further disclose the size and morphology of the calcium phosphate particles can be readily controlled by adjusting the reactant concentrations, solution pH, reaction heating rate, mixing reaction temperature, and length of reaction (Roeder et al., 0045).

36. The difference between the process of Roeder et al. and that of **Claim 10** is Roeder et al. do not disclose "highly" crystalline calcium phosphate, first preparing the calcium salt solution and then adding the phosphate solution to the calcium salt solution, adjusting the pH of the solution to a selected value of between 4 and 6, adding the phosphate solution over a period of time of between 30 minutes and 4 hours, so as to obtain a calcium to phosphorous molar ratio of between 1 and 2.5, wherein the pH is maintained constant at the selected value of between 4 and 6, nor at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

37. The difference between the process of Roeder et al. and that of **Claim 11** is Roeder et al. do not disclose "highly" crystalline calcium phosphate, first preparing the calcium salt solution and then adding the phosphate solution to the calcium salt solution, adjusting the pH of the solution to a selected value of between 4 and 6, adding the phosphate solution over a period of time of between 30 minutes and 4 hours, so as to obtain a calcium to phosphorous molar ratio of between 1 and 2.5, wherein the pH is maintained constant at the selected value of between 4 and 6, adjusting the pH of the solution to a value of between 8 and 9.5, nor at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm.

38. Roeder et al. do not disclose a calcium phosphate platelet thickness of between 1 nm and 40 nm (**Claim 3**); the platelets exhibiting a chemical shift of between -1.4 ppm and -1 ppm, as measured by phosphorous-31 MAS NMR (**Claim 4**); the concentration of calcium salt in the solution of calcium salt between 1M and 2.5M (**Claims 13 and 20**); the phosphate solution being a solution of $(NH_4)_2(HPO_4)$ or $(NH_4)(H_2PO_4)$ (**Claims 14 and 21**); nor the calcium to phosphate molar ratio between 1.3 and 1.7 (**Claims 15 and 22**).

39. With regard to the "highly" crystalline calcium phosphate of **Claims 1, 10 and 11**, "highly crystalline" was interpreted as "crystalline" or "crystals" since "highly crystalline" is not defined by the Claims, the Specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. *See* 35 U.S.C. 112, second paragraph, rejection above. Thus, the crystalline calcium phosphate platelets of Roeder

et al. would be "highly crystalline." In any event, no other calcium phosphate structure besides crystalline is disclosed by Roeder et al. and thus, the crystalline calcium phosphate platelets of Roeder et al. would be "highly crystalline" because of the absence of any other calcium phosphate structure.

40. With regard to the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claims 1, 10 and 11**, the claimed particle size range overlaps the range disclosed by Roeder et al. and thus, a *prima facie* case of obviousness exists. *See* In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); In re Geisler, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997). Optimization of the platelet size range would have been obvious to one of ordinary skill in the art. *See* Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382; In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Roeder et al. disclose that the size and morphology of the particles can be controlled by adjusting various reaction parameters (Roeder, 0045).

41. With regard to the at least 80% of the calcium phosphate platelets having a length of between 250 nm and 800 nm of **Claims 1, 10 and 11**, Roeder et al. disclose the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder et al., 0035). If the average particle size of the calcium phosphate platelets of Roeder et al. in the range of 1 nm and 500 nm is 480-500 nm, then at least 80% of the calcium

phosphate platelets of Roeder et al. would most surely have a length of between 250 nm and 800 nm. In any event, optimization of the platelet size would have been obvious to one of ordinary skill in the art. Roeder et al. disclose that the size and morphology of the particles can be controlled by adjusting various reaction parameters (Roeder, 0045).

42. With regard to **Claim 3**, an expected platelet thickness is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such thickness varies. Roeder et al. disclose that the size and morphology of the particles can be controlled by adjusting various reaction parameters (Roeder, 0045). Since the platelet thickness is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable calcium phosphate platelet thickness. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

43. With regard to **Claim 4**, the platelets of Roeder et al. would be expected to exhibit a chemical shift of between -1.4 ppm and -1 ppm, as measured by phosphorous-31 MAS NMR since the platelets of Roeder et al. have a monetite structure (Roeder et al., Table 1).

44. With regard to the order of preparing and adding the calcium salt solution and phosphate solution of **Claims 10 and 11**, selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. *See* In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946); Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959); and In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930).

45. With regard to **Claims 10 and 11**, solution pH is a result effective variable, as evidenced by Roeder et al. (Roeder et al., 0045). Roeder et al. disclose the size and morphology of the calcium phosphate particles can be readily controlled by adjusting the solution pH (Roeder et al., 0045). Since the solution pH is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable pH of the solution. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

46. With regard to **Claims 10 and 11**, length of reaction is a result effective variable, as evidenced by Roeder et al. (Roeder et al., 0045). Roeder et al. disclose the size and morphology of the calcium phosphate particles can be readily controlled by adjusting the length of reaction (Roeder et al., 0045). Since the length of reaction is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable time period for the addition of the phosphate solution. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

47. With regard to **Claims 10, 11, 15 and 22**, reactant molar ratio is a result effective variable since one of ordinary skill in the art would expect different properties in the process and resulting product as such parameter varies. Since the reactant molar ratio is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable calcium to phosphate molar ratio. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

48. With regard to **Claims 13 and 20**, reactant concentration is a result effective variable, as evidenced by Roeder et al. (Roeder et al., 0045). Roeder et al. disclose the size and morphology of the calcium phosphate particles can be readily controlled by

adjusting the reactant concentrations (Roeder et al., 0045). Since the reactant concentration is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable concentration of calcium salt in the solution of calcium salt. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

49. With regard to **Claims 14 and 21**, Roeder et al. disclose the phosphate solution being a solution of ammonium orthophosphate or the like (Roeder et al., 0044). The various ammonium phosphates (including $(NH_4)_2(HPO_4)$ or $(NH_4)(H_2PO_4)$) would have been obvious to one of ordinary skill in the art in view of the "ammonium orthophosphate, and the like" of Roeder et al. (Roeder et al., 0044) (emphasis added).

50. **Claims 14 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Roeder et al. (US 2003/0031698 A1) (of record) as applied to **Claims 10 and 11** above, and further in view of Kumta et al. (US 7,247,288 B2) (of record).

51. With regard to **Claims 14 and 21**, Roeder et al. disclose the phosphate solution being a solution of ammonium orthophosphate or "the like" (Roeder et al., 0044).

52. Roeder et al. do not disclose the phosphate solution being a solution of $(NH_4)_2(HPO_4)$ or $(NH_4)(H_2PO_4)$ (**Claims 14 and 21**).

53. With regard to **Claims 14 and 21**, Kumta et al. disclose a method for preparing nanocrystalline calcium phosphate platelets (Kumta et al., "Abstract") comprising the steps of: preparing a solution of calcium salt ($CaCl_2$ or $Ca(NO_3)_2$) (Kumta et al., c. 1, l. 66; c. 4, l. 53-57; c. 8, l. 27-35); adding a phosphate solution ($(NH_4)_2(HPO_4)$) (Kumta et al., c. 1, l. 66; c. 8, l. 35-41) to the calcium salt solution (Kumta et al., c. 14, l. 58-67; c.

15, l. 1-3; c. 18, l. 27-32 and 40-47), so as to obtain a calcium to phosphorus molar ratio of greater than 1.67 (Kumta et al., c. 4, l. 48-51), wherein the pH is maintained constant (Kumta et al., c. 6, l. 8-18); heat treating the solution (Kumta et al., c. 15, l. 5-8; c. 18, l. 50-53); and separating the calcium phosphate platelets formed from the solution (Kumta et al., c. 15, l. 5-8).

54. Thus, it would have been obvious to one of ordinary skill in the art to try to modify the process disclosed by Roeder et al. with $(NH_4)_2(HPO_4)$ as taught by Kumta et al. because one of ordinary skill in the art could have pursued the known potential phosphate solution options within his or her technical grasp with a reasonable expectation of success.

***Double Patenting***

55. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

56. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

57. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

58. **Claims 1-5, 9-15, 17 and 19-22** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-6 of U.S. Patent No. 7,807,724 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending U.S. Patent No. 7,807,724 B2 discloses a composition comprising a dispersion of separated calcium phosphate platelets and a process for making such, substantially as in the instant claims.

***Response to Amendment***

Applicants' amendment filed on June 21, 2010, with respect to the Claims has been fully considered and is accepted.

***Response to Arguments***

59. Applicants' arguments filed June 21, 2010, with regard to the 35 U.S.C. 102 rejections of the instant Claims over Itoi et al. and Roeder et al. (Applicants' Response, 6/21/10, p. 6-8) have been fully considered but they are not persuasive.

60. Applicants' argument that Itoi et al. do not disclose an aqueous dispersion or precipitate of separated calcium phosphate platelets (Applicants' Response, 8/21/09, p. 7) is not convincing. First, it is noted that the instant Claims do not recite a precipitate of separated calcium phosphate platelets. Second, while Itoi disperses the calcium phosphate particles in an organic solvent (Applicants' Response, 8/21/09, p. 7), the dispersion may comprise water in addition to the organic solvent (Itoi et al., c. 3, l. 36-46).

61. Applicants' argument that Itoi et al. do not disclose an aqueous dispersion wherein at least 80% of the platelets are between 250-800 nm in length (Applicants' Response, 8/21/09, p. 7) is not convincing. Itoi et al. disclose apatite crystals with a short axis length of 30 to 300 nm and a long-axis length of 100 to 1000 nm (Itoi et al., c. 3, l. 29-31). At least 80% of the calcium phosphate platelets of Itoi et al. would inherently have a length of between 250 nm and 800 nm. For a reference which neither expressly describes or teaches the subject matter alleged to be anticipated, the

reference must provide enough information to permit an inference that the subject matter is inherent. *Ex parte Garvin*, 62 USPQ 2d 1680 (BPAI 2001). If the average particle size of the calcium phosphate platelets of Itoi et al. in the range of 100 to 1000 nm is 500 nm, then at least 80% of the calcium phosphate platelets of Itoi et al. would most surely have a length of between 250 nm and 800 nm. Accordingly, the burden shifts to Applicants to show that the calcium phosphate platelets of Itoi et al. would not have at least 80% of the calcium phosphate platelets with a length of between 250 nm and 800 nm. In any event, optimization of the platelet size would have been obvious to one of ordinary skill in the art. While the primary particles of Itoi et al. eventually aggregate into particles having a size of 1 micrometer or more (Applicants' Response, 8/21/09, p. 7), the nanosize primary particles would initially be "separated" before said purposeful agglomeration. Thus, at some point, there would be a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a short axis length of 30 to 300 nm and a long-axis length of 100 to 1000 nm (Itoi et al., c. 3, l. 29-31).

62. Applicants' argument that Roeder et al. do not disclose an aqueous dispersion or precipitate of separated calcium phosphate platelets (Applicants' Response, 8/21/09, p. 8) is not convincing. First, it is noted that the instant Claims do not recite a precipitate of separated calcium phosphate platelets. Second, while Roeder et al. disclose the calcium phosphate dispersed within a thermoplastic polymer (Applicants' Response, 8/21/09, p. 8), the thermoplastic polymer dispersion may further comprise water (Roeder et al., 0031). Third, the teaching by Roeder et al. that "dispersed" does not

precluded does not give rise to the conclusion that contact is required.

63. Applicants' argument that Roeder et al. do not describe separated calcium phosphate platelets because the examples of Roeder et al. drawn to particles having an average particle size of 2-3 microns or an average length of 20 microns (Applicants' Response, 8/21/09, p. 8) is not convincing. First, a prior art reference is not limited to the teachings of the examples. Rather, the prior art reference is viewed in its entirety and further in view of what it may reasonably suggest to one of ordinary skill in the art. Second, at some point, the composition of Roeder et al. would be a composition comprising separated calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder et al., "Abstract;" Fig. 2; Table 1; 0014; 0031; 0033; 0035; 0047).

64. Applicants' argument that Roeder et al. do not disclose an aqueous dispersion wherein at least 80% of the platelets are between 250-800 nm in length (Applicants' Response, 8/21/09, p. 8) is not convincing. Roeder et al. disclose the calcium phosphate platelets have a mean length of between 1 nm and 500 nm (Roeder et al., 0035). At least 80% of the calcium phosphate platelets of Roeder et al. would inherently have a length of between 250 nm and 800 nm. For a reference which neither expressly describes or teaches the subject matter alleged to be anticipated, the reference must provide enough information to permit an inference that the subject matter is inherent. *Ex parte Garvin*, 62 USPQ 2d 1680 (BPAI 2001). If the average

particle size of the calcium phosphate platelets of Roeder et al. in the range of 1 nm and 500 nm is 480-500 nm, then at least 80% of the calcium phosphate platelets of Roeder et al. would most surely have a length of between 250 nm and 800 nm. Accordingly, the burden shifts to Applicants to show that the calcium phosphate platelets of Roeder et al. would not have at least 80% of the calcium phosphate platelets with a length of between 250 nm and 800 nm. In any event, optimization of the platelet size would have been obvious to one of ordinary skill in the art.

65. Applicants' arguments filed June 21, 2010, with regard to the rejection of the instant Claims over Lee et al. (Applicants' Response, 6/21/10, p. 7-8) have been fully considered and are persuasive to the extent Lee et al. disclose amorphous, not crystalline, calcium phosphate. The only crystalline calcium phosphate Lee et al. disclose is poorly crystalline apatitic calcium phosphate (Lee et al., p. 4; p. 6). The corresponding rejection has been withdrawn.

66. Applicants' arguments filed June 21, 2010, with regard to the 35 U.S.C. 103 rejections of the instant Claims (Applicants' Response, 6/21/10, p. 9-13) have been considered but are moot in view of the new ground(s) of rejection.

67. It is noted that, besides the mention of a terminal disclaimer (Applicants' Response, 6/21/10, p. 13), Applicants did not address the nonstatutory obviousness-type double patenting rejection of the previous Office action. The corresponding rejection stands (and is modified); however, the rejection is no longer provisional in view of the patenting of copending U.S. Application No. 10/563167 as U.S. Patent No. 7,807,724 B2.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRITTANY M. MARTINEZ whose telephone number is (571) 270-3586. The examiner can normally be reached on Monday-Friday 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Emily M. Le can be reached on (571) 272-0903. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wayne Langel/
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